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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,362	12/12/2003	Diana J. Parsons	parsons 3	1804
40198 7590 04/01/2008 BUSH INTELLECTUAL PROPERTY LAW GROUP, LLC P.O. BOX 381146 BIRMINGHAM, AL 35238				
EXAMINER				
LANDAU, SHARMILA GOLLAMUDI				
ART UNIT		PAPER NUMBER		
1611				
MAIL DATE		DELIVERY MODE		
04/01/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/735,362

Applicant(s)

PARSONS, DIANA J.

Examiner

Sharmila Gollamudi Landau

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21, 23-29 and 33-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21, 23-29, 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of Amendments/Remarks filed 1/7/08 is acknowledged. Claims 1-20, 22, and 30-32 stand cancelled. Claims 21, 23-29, 33-37 are pending.

Response to Arguments

The amendments filed 1/7/08 necessitate new grounds of rejections. However, since the amended claims are still rejected under 112, 1st, the examiner will address certain arguments that are pertinent.

Applicant argues that the use of the word “stratum corneum” was in error and the word that should have been used was particles. Applicant argues that US 6,036,684 which is incorporated by reference discloses that a first and second pulse cleans the particles off.

Applicant's arguments filed 1/7/08 have been fully considered but they are not persuasive. It appears applicant is arguing that an “obvious error” was made. The examiner directs applicant's attention to MPEP 2163: An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction. In re Oda, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971). In instant case, the use of the term “stratum corneum” is not an obvious error. The examiner notes that applicant incorporates by reference the process disclosed in US 6,036,684. As acknowledged by applicant Tankovich teaches removing the stratum corneum by exploding the stratum corneum. It is noted that applicant argues that the stratum corneum only explodes after the third pulse and the first and second pulse do not remove the stratum corneum. However, page 7 of the originally filed specification disclosed, “Once the contaminant or activating solution is applied to the skin, the laser treatment can begin. The

energy from the laser is adjusted to be just sufficient to cause the particles to explode. As the particles explode, they cause the removal of the stratum corneum and the mineral oil 20 penetrates into the epidermis producing hydration of the epidermis by retarding the evaporation of water (see Fig. 2)." The specification does not discuss the number of pulses or the correlation of the pulses and removal of skin versus particles. Therefore, as acknowledged by applicant, Tankovich teaches removing the stratum corneum by exploding the particles. Additionally, Figure 3 of the instant specification discloses, "Move laser across skin to explode the graphite particles and reveal the underlying skin". Therefore, this disclosure clearly indicates that skin is removed. Thus, the use of the word "stratum corneum" is not an obvious error.

Applicant argues the instant invention is enabled and it is not necessary to know the mechanism the process work as long as a skilled artisan can duplicate the steps. Applicant argues that it is inherent that one or two pulses do not remove hair or skin and it is inherent that following the instant method steps will provide skin rejuvenation.

First, the examiner points out that the recitation "one or two pulses" is considered new matter as set forth below. Second, the examiner acknowledges that enablement does not require that the invention provide the underlying mechanism in which the end result is attained. However, enablement requires providing sufficient parameters of the method to "use" the invention as claimed. In instant case, applicant has not provided any parameters pertaining to the number of pulses or the correlation of the number of pulses and other factors such as fluence, wavelength, etc. The only contemplation of pulses is derived by the Tankovich's process, which is incorporated by reference. Thus, Tankovich's process (which utilizes at least three pulses) is necessarily present in the instant specification and is part of the guidance of the specification.

Tankovich teaches the same laser, the same pulse duration, the same fluence, and wave length, and teaches that the third pulse provides the cosmetic benefit. Both US '684 and US '803 are directed to removing skin, the stratum corneum, to attain cosmetic benefit by using at least 3 pulses. US '684 discloses that about 5 pulses are required to treat acne. US '803 discloses that to remove skin pigmentation such as a tattoo, removal of the skin is necessary. Applicant has not provided any parameters for the process using only one to two pulses and the method of achieving the benefit using only one to two pulses. Moreover, applicant has not even contemplated the use of *only* one or two pulses, which raises a written description issue. Clearly applicant does not have possession of a method that uses only one or two pulses. The entire disclosure is directed to three pulses that removes some skin to attain a cosmetic benefit. A skilled artisan would not know how to use the instant invention after reading the instant disclosure, which necessarily contains Tankovich's process that utilizes three pulses. It is further noted that the instant specification is directed to "revealing underlying skin" and "skin resurfacing". Again, a skilled artisan would be know how to achieve these benefits without removing skin or using only one or two pulses since the entire specification is directed to removing skin and using at least three pulses. Moreover, a skilled artisan would not know what the fluence, the wavelength, pulse duration, etc. is for a method using only one or two pulses.

Applicant argues that the instant specification does contain working examples. Applicant shows the effects of the instant method on a patient suffering from acne.

The examiner notes Figure 4. However, applicant does not specify the parameters of the process. Again, the examiner points out that the specification incorporates Tankovich's process by reference. The only contemplation of the number of pulses used to provide skin rejuvenation,

let alone improve acne, can only be derived from Tankovich's process. Tankovich discloses the use of about 5 pulses. Thus, clearly the instant invention is not enabled for treating acne using only one or two pulses since the instant specification teaches about 5 pulses to treat acne. Further, applicant does not have written description for using one to two pulses for improving acne.

Applicant argues that the instant invention is not unpredictable since Tankovich teaches the use of one or two pulses do not remove skin. Further, applicant argues Figure 3 of the instant specification discloses, "Move laser across skin to explode the graphite particles and reveal the underlying skin".

First, it is the examiner's position and as outlined in the rejection below, that Tankovich does not clearly state that the first and second pulse does not remove *any* skin. Tankovich discloses that majority of the skin is removed during administration of the third pulse. This is not equivalent to the teaching that the first and second pulse do not remove *any* skin cells whatsoever. Applicant reference to Figure 3 supports the examiner's position that one cannot use the invention as claimed. "Revealing the underlying skin" is implicit that the skin above is removed. Clearly applicant's process includes removing skin. Thus, a skilled artisan cannot attain the cosmetic benefit without removing at least *some* skin.

Specification

The amendment filed 6/22/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The entire added text (underlined portion) is considered new

matter for the following reasons: The examiner notes that page 5, line 24 incorporates US 6,036,684 by reference in accordance to MPEP 60.8.01. The instant specification states discloses, "The Tankovich processes disclosed in U.S. Patent No. 5,423,803 and U.S. Patent No. 6,036,684 are incorporated herein by reference." However, it is noted that applicant "cuts and pastes" portions of Tankovich's process into the instant process spanning page 6 to 7. It appears applicant is attempting to simultaneously include and exclude certain portions of Tankovich's process. However, the originally field specification clearly states that Tankovich's process is "incorporated by reference". Thus, applicant cannot include certain portions and exclude other portions since the original specification incorporated the entire process. Applicant has amended the specification to recite Tankovich's process between applicant's process. For instance, applicant has inserted Tankovich's process "is to irradiate the skin surface with Nd:YAG laser pulses of about 3 J/cm² at a wavelength of 1.06 micrometers. Pulse frequency is about 5 Hz but we scan the beam so that each location is subjected to pulses at a frequency of about 1 Hz" before applicant's disclosure "for the creation of a chronic wound selectively in the high dermis." However, Tankovich does not teach this process produces a chronic wound and thus this is new matter. Further, applicant has excluded Tankovich's process in lines 10-24.

Second, it is noted that applicant has pieced together Tankovich's process. When a reference is incorporated by reference, applicant cannot "re-formulate" the disclosure of the referenced patent. For instance, applicant has inserted the disclosure of column 5, line 42-49 into column 4 of Tankovich's process. Tankovich does not disclose the recited portion, "The first or second pulses clean substantially all of the mixture from the skin surface by violently fracturing the carbon particles. By observing how many particles remain, the doctor can estimate the degree

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to which each area has been treated. For hair removal, the beam is scanned over the area to be treated with each section of the skin in the area receiving about 5 pulses. The energy is sufficient to devitalize the tissue feeding the hair so the hair dies” on column 4 *after* “the particles explode violently ripping off the dead cells of the stratum corneum which lay above the exploding cells.” The disclosure of column 5 (“The first or second pulses clean substantially all of the mixture from the skin surface by violently fracturing the carbon particles. By observing how many particles remain, the doctor can estimate the degree to which each area has been treated. For hair removal, the beam is scanned over the area to be treated with each section of the skin in the area receiving about 5 pulses. The energy is sufficient to devitalize the tissue feeding the hair so the hair dies”) is limited to hair removal and does not relate to column 4 which is directed to Pulse Irradiation. Applicant cannot merge the columns together. The recitation, “For hair removal, the beam is scanned over the area to be treated with each section of the skin in the area receiving about 5 pulses. The energy is sufficient to devitalize the tissue feeding the hair so the hair dies” is also pieced together.

Therefore, although it is noted that US 6,036,684 is incorporated by reference, the amendments to the specification are considered new matter for the reasons discussed above.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 23-29, 33-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that: To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

Applicant's claim amendment filed 6/22/07 "does not remove skin or hair" does have support in originally filed specification. It is noted that applicant has amended the specification on 6/22/07 to exclude the phrase, "the removal of the stratum corneum". The *originally* filed specification disclosed, "The energy from the laser is adjusted to be just sufficient to cause the particles to explode. As the particles explode, they cause the removal of the stratum corneum and the mineral oil 20 penetrates into the epidermis producing hydration of the epidermis by retarding the evaporation of water (see Fig. 2)."

First, page 5 of the specification is noted in which applicant discloses, "The Tankovich processes disclosed in U.S. Patent No. 5,423,803 and U.S. Patent No. 6,036,684 are incorporated

herein by reference.” Thus, the instant specification incorporates the entire *process* of US 6,036,684 and US 5,423,803.

Applicant filed an amendment to the specification on 1/7/08 inserting portions of Tankovich's (US 6,036,684) process. The portions inserted recite, “Laser energy at 1.06 wavelength has an extinction length in human skin of several millimeters but is highly absorbed in the graphite particles below the surface and upon absorption of the energy from the third pulse, the particles explode violently ripping off the dead cells of the stratum corneum which lay above the exploding cells.” Further, a portion recites, “The skin is fairly effectively shielded from the pulse by the second layer. But the third pulse interacts with the skin and the carbon particles below the skin.” “Fairly” shielded clearly indicates that *some* of the skin is removed during the second pulse. Neither the instant specification nor US 6,036,684 ever state that the first and second pulse never remove any skin cells. US 5,423,803 to Tankovich which is also incorporated by reference discloses, “A process for the removal of superficial epidermal skin cells in human skin comprising the steps of: a. topically applying to a section of said skin a contaminant having a high absorption at least one frequency band of light which penetrates the outer layers of human epidermis, b. forcing some of said contaminant to infiltrate into spaces between said superficial epidermal skins cells, and c. illuminating said section of skin with pulses of said at least one frequency band of light, at least one of said pulses having sufficient energy to cause at least a portion of said contaminant to explode so as to tear off some of said superficial epidermal skin cells.” Clearly US ‘803, which is incorporated in its *entirety*, is not only directed to removing skin, US ‘803 indicates that any of the pulses can remove *some* skin. Additionally, the instant specification on page 6, discloses that retinoic acid attacks the cell glue

making the stratum corneum thinner. Applicant's process is directed to applying retinoic acid as a pretreatment. Thus, the stratum corneum is in a weakened condition. Therefore, since the "glue" that adheres the cells together is weakened, the force of the explosion in the first and second pulse will remove at least *some* of the weakened skin cells. The examiner points out that even if a few skin cells are removed, that is enough to render the recitation, "does not remove skin" new matter.

Further, it is noted that applicant argues that only the third pulse removes skin and applicant excludes removal of any skin; however the Figure 3 of the instant specification discloses, "Move laser across skin to explode the graphite particles and reveal the underlying skin". Clearly, the underlying skin cannot be revealed unless skin is removed. The instant specification discloses "wounding" the skin and page 6, line 2 discloses, "beginning at the sixth month from the initial wounding, a series of booster laser treatments is given until the desired skin resurfacing end point is reached." The definition of a wound is "An injury, especially one in which the skin or another external surface is torn, pierced, cut, or otherwise broken." Thus, wounding implies removal of *some* skin. Moreover, applicant clearly discloses the process resurfaces the skin. Applicant utilizes a laser and clearly discloses on page 6, line 2 that the skin is resurfaced. Note the attached definitions. Laser *resurfacing* is known to remove skin. <http://www.surgeryencyclopedia.com/La-Pa/Lascr-Skin-Resurfacing.html> discloses, "The purpose of laser skin resurfacing is to use the heat generated by extremely focused light to remove the upper to middle layers of the skin." Lastly, examiner notes that skin rejuvenation includes improving scars, acne, skin pigmentation, etc. Again it is noted that applicant incorporates US 5,423,803 in its entirety. US '803 process as discussed above is directed to

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removing skin. US '803 discloses removing tattoos (reads on improving skin pigmentation) by removing the skin. Thus, applicant does not have support for completely excluding any removal of skin.

Applicant has amended the claims to recite “one or two pulses” which does not have support in the specification as originally filed nor does the specification satisfy the written description requirement. Applicant states that US 6,036,684 has been incorporated by reference. Again it is reiterated that applicant has incorporated by reference the entire process disclosed by Tankovich, which is directed to using three pulses to achieve the cosmetic benefit. Applicant is attempting to simultaneously include and exclude certain portions of Tankovich's process. However, this is considered new matter since applicant is attempting carve around Tankovich as prior art even though the instant specification discloses that the entire Tankovich process (both US 6,036,684 and US 5,423,803) is used in applicant's invention. Moreover, the instant specification does not contemplate that only two pulses versus three pulses are required to attain the skin rejuvenation. In fact, the instant specification does not even discuss the number of pulses required to attain skin rejuvenation. Thus, there is insufficient written description of using one to two pulses to attain skin rejuvenation. The only contemplation of pulses can be derived by the incorporation of Tankovich's process, which clearly does not disclose the use of only two pulses to achieve a cosmetic benefit. Thus, applicant's incorporation of Tankovich's process does not provide adequate written description of the instant recitation of using only one to two pulses to *attain a cosmetic benefit* since a skilled artisan would readily ascertain when reading the instant disclosure (which incorporates both US 6,036,684 and US 5,423,803) that applicant has only possession of a method using three or more pulses. Figure 3 of the instant specification

discloses, “Move laser across skin to explode the graphite particles and reveal the underlying skin”. Therefore, this disclosure clearly indicates that skin is removed. Applicant argues that *only* the third pulse removes skin; thus clearly the instant invention is not directed to only one or two pulse since applicant is revealing the underlying skin by removing skin (note the discussion above). Lastly, the examiner notes that skin rejuvenation includes improving scars, acne, skin pigmentation, etc. US 6,036,684 discloses on column 6, lines 20-25, “Our preferred process for treatment of acne and seborrhea is basically the same as the treatment for hair removal and skin peeling.” On column 5, lines 43-45, US ‘684 discloses the use of about 5 pulses to remove hair. Thus, clearly applicant does not have support for treating acne with only one or two pulses since applicant incorporates US ‘684 in its entirety. Again the contemplation of the number of pulses utilized in the instant invention can only be derived by Tankovich’s process. Therefore, applicant not only does not have support for using only one to two pulses but applicant does not have sufficient written description to utilize one or two pulses to provide the instant cosmetic benefit, which includes treating acne.

It should be noted that once the new matter rejections are removed, prior art will be applied to reject the claims.

Claims 21, 23-29, 33-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in the view of the Wands factors (MPEP 2164.01 (a)). These include the nature of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, and state of the prior art. All of the Wands factors have been considered with the regard to the instant claims, with the most relevant discussed below. The instant claims are not enabled to prevent healing of the skin indefinitely and the process of treatment by prevention of healing.

Nature of the Invention: The rejected claims are drawn to the method of producing sustained skin rejuvenation comprising: a) pre-treating the skin with a retinoic acid; b) exploding a contaminant on the skin surface using one to two pulses without removing skin using a wavelength of 800-1200nm, a fluence of 1-3 J/cm², and a pulse duration of 0.001-1 microsecond; c) applying retinoic acid to the skin 4-16 times after step b, and d) repeating treatment once every twelve months. Skin rejuvenation includes improving acne, wrinkles, scars, skin pigmentation, etc.

Breadth of the claims: The breadth of the claim encompasses preventing any skin removal after exploding a contaminant such as graphite or carbon using a laser and only using one to two pulses to attain skin rejuvenation which includes acne, wrinkles, scars, skin pigmentation, etc.

Guidance of the Specification: The instant specification incorporates the entire *process* of US 6,036,684 to Tankovich et al and US 5,423,803 to Tankovich et al. Therefore, Tankovich's disclosure is necessarily present in the instant specification and is part of the guidance of the specification. Both US '684 and US '803 are directed to removing skin to attain cosmetic benefit using at least 3 pulses. US '684 discloses that about 5 pulses are required to treat

acne. US '803 discloses that to remove skin pigmentation such as a tattoo, removal of the skin is necessary. Figure 3 of the instant specification discloses the method in which the cosmetic benefit is attained: "Move laser across skin to explode the graphite particles and reveal the underlying skin". Further, the instant specification discloses on page 6, line 2 discloses, "beginning at the sixth month from the initial wounding, a series of booster laser treatments is given until the desired skin resurfacing end point is reached." Therefore, the guidance of the specification is directed to removing at least some skin to attain the cosmetic benefit. However, applicant's specification does not describe a method using only one to two pulses and the parameters of the laser for a one to two pulse treatment. For instance, it is unclear what the setting of the wave length, the pulse duration, and the fluence is for a one or two pulse treatment and if this setting changes with the type of skin improvement. For instance, the specification does not provide any guidance of the parameters of treating wrinkles versus treating infections, veins, etc. The only guidance of the parameters and number of pulses in correlation with the given treatment is from Tankovich.

The State of the Art: <http://www.surgeryencyclopedia.com/La-Pa/Laser-Skin-Resurfacing.html> discloses, "Laser skin resurfacing involves the application of laser light to the skin in order to remove fine wrinkles and tighten the skin surface. The purpose of laser skin resurfacing is to use the heat generated by extremely focused light to remove the upper to middle layers of the skin." Thus, the instant specification discloses using "skin resurfacing" on page 6 to render the cosmetic benefit and the state of the art indicates that "skin resurfacing" is the removal of skin. Therefore, if the skin is not removed, as argued by applicant since only 1-2 pulses are used, then the skin is not resurfaced and the cosmetic benefit is not attained.

As discussed above, US 6,036,684, to Tankovich, discloses an identical process using the same fluence, pulse duration, and wavelength. Tankovich discloses that about 5 pulses are required to treat acne. Applicant incorporates Tankovich's process by reference. Thus, clearly indicating that one or two pulses will not achieve the cosmetic benefit of treating acne as claimed in dependent claim 36.

The laser art indicates that there is nonablative laser surgery and ablative laser surgery. In ablative laser surgery, a laser works by vaporizing the top layer of the skin to remove blemishes, scars and wrinkles. <http://ivseasonsskincare.com/NAR.html> discloses, "Non-Ablative Skin Rejuvenation is a non-surgical process that gives significant improvement in mild to moderate skin lines by combining gentle light laser treatments with Particle Skin Resurfacing (PSR). The results of Non-Ablative Rejuvenation procedures are much more subtle and gradual than those obtained with ablative procedures such as the Carbon Dioxide or Erbium Lasers. Non-Ablative Skin Rejuvenation aims to bypass the injury to the epidermis while stimulating collagen remodeling with dermal heating, as well as significantly improving red vessels and lesions. The instant invention is directed to non-ablative procedures since applicant uses a laser with PSR to stimulate collagen production. <http://www.plasticsurgeryadvisor.com/skin-resurfacing-surgery/non-ablative-laser-surgery.shtml> discloses in non-ablative laser surgery, the laser removes tissue beneath the first layer of skin (in the epidermis).

Therefore, the prior art indicates that some skin either in the stratum corneum or beneath the stratum corneum will be removed by laser surgery to attain cosmetic benefits.

Working Examples: Figure 4 shows the effect of "laser method of the present invention on the restoration of the skin of a patient suffering from acne vulgaris". It is noted that the

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specification incorporates Tankovich's laser method by reference. Note page 5. The only contemplation of the number of pulses used to provide skin rejuvenation, let alone improve acne can only be derived from Tankovich's process, which is incorporated by reference. Tankovich discloses the use of about 5 pulses.

Predictability of the Art: The lack of significant guidance from the specification or the prior art with regard to exploding a contaminant using lasers and only one or two pulses and preventing the removal of any skin to attain a cosmetic benefit makes practicing the instant invention unpredictable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 21, 23-29, 33-37 under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al (Skin resurfacing utilizing a low-fluence Nd:YAG laser, J Cutan Laser Ther. 1999;1:23-27) in view of Alster (Combined Laser Resurfacing

and Tretinoin Treatment of Facial Rhytides, Cosmetic Dermatology, Volume 10, No. 11, November 1997) in view of Ho et al (Dermatologic Surgery. 1995 December, 21(12), 1035-7) and Kye YC (Dermatologic Surgery 1997 October, 23(10): 880-883) is withdrawn in light of applicant's amendment. However, the rejection will be reinstated once the new matter is removed.

Pertinent Prior Art

Goldberg et al (Skin resurfacing utilizing a low-fluence Nd:YAG laser, J Cutan Laser Ther. 1999;1:23-27) is cited as pertinent prior art. Goldberg et al teach nonablative skin resurfacing using 1064-nm Q-switched Nd:YAG laser potentiated by a carbon solution at a fluence of 2.5J/cm, repetition rate of 1-10 HZ, and a pulse duration of 6-20ns to treat rhytides (wrinkles).

Conclusion

All the claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharmila Gollamudi Landau/
Primary Examiner, Art Unit 1611